IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 13 CASES LISTED IN EXHBIT A OF DEFENDANTS' MOTION**	

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS'
MOTION TO EXCLUDE THE GENERAL OPINIONS OF STACEY WALLACH, M.D.

COMES NOW, Plaintiffs and file their Response in Opposition to Defendants' Ethicon Inc. and Johnson & Johnson, Inc.'s ("Ethicon") Motion Exclude the General Opinions and Testimony of Stacey Wallach, M.D. (Dkt. No. 8994), and show as follows:

INTRODUCTION

Dr. Wallach is Board Certified in both Obstetrics and Gynecology, and she has a subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery (FPRMS). *See* Ex. 1, Curriculum Vitae of Dr. Wallach. Dr. Wallach has been at the University of California-Davis since 2002 when she finished her three-year fellowship in urogynecology/female reconstructive surgery. She is a Professor of Obstetrics and Gynecology/Urogynecology at UC-Davis, and she has been the Director of Urogynecology and Pelvic Reconstructive Services at UC-Davis since 2003. Dr. Wallach is an oral examiner for the American Board of Obstetrics and Gynecology, and she is a member of the American College of Obstetrics and Gynecology, the Association of Professors of Gynecology and Obstetrics, the American Urogynecologic Society, the International Urogynecological Association and the International Continence Society. She

has been a reviewer for the American Journal of Obstetrics and Gynecology since 2005. *Id.* Ethicon seeks to exclude all or part of Dr. Wallach's "General" opinions on various grounds. As set forth below, the Court should deny this motion in its entirety.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The first prong is aimed at excluding so-called "junk science." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993). Courts should examine whether the reasoning or methodology underlying the expert's preferred opinions is reliable. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 257 (4th Cir. 1999); *Daubert*, 509 U.S. at 593. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

"The inquiry to be undertaken by the district court is a flexible one." *Westberry*, 178 F.3d at 261, *Daubert*, 509 U.S. at 594–95; *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). In the end, an expert's testimony is admissible under Rule 702 if it "rests on a reliable foundation and is relevant." *Kuhmo Tire*, 526 U.S. at 141. The court's focus in a *Daubert* inquiry should be

solely on the expert's "principles and methodology, not on the conclusions they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

Weaknesses in the underpinnings of the expert's opinion go to the opinion's weight, rather than its admissibility. *Pugh v. Louisville Ladder, Inc.*, 361 Fed. Appx. 448, 456 (4th Cir. 2010). Rejection of expert testimony is to be the "exception rather than the rule." *United States v. Stanley*, 533 Fed. Appx. 325, 327 (4th Cir. 2013). The proponent need not prove that the expert's testimony is correct, as the validity of the expert's conclusions is for the finder of fact to determine. *Westberry*, 178 F.3d at 261. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the "traditional and appropriate" means of attacking expert testimony. *Daubert*, 509 U.S. at 596; *Cavallo v. Star Enterprise*, 100 F3d 1150, 1158 (4th Cir. 1996).

LEGAL ARGUMENT

I. Dr. Wallach's Opinions regarding the Prolift have been properly and appropriately disclosed and they should be permitted as they provide the necessary foundation for her case specific opinions.

As an initial matter, Ethicon's position on Dr. Wallach's "general" causation opinions is inconsistent with its arguments in prior waves. Ethicon argues, as an initial matter, that Dr. Wallach "inappropriate[ly]" offers general opinions regarding Ethicon's Prolift mesh, and that she cannot offer general causation opinions because she has not been disclosed as a general causation expert.[1] Ethicon's position is remarkable, given the position it has taken with regard to certain experts in the past. On several occasions, Ethicon has argued that a particular expert should be excluded from offering case-specific testimony due to **a lack of general causation testimony**. *See, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-03074, 2017 WL 2214895, at *2 (S.D.W. Va. May 18, 2017) ("Ethicon argues that I should exclude Dr. Walmsley's specific causation testimony because it is insufficiently grounded in general causation testimony."); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No.

[1] Defendant's Memo in Support of Motion at p. 3-4

2327, 2017 WL 532124, at *2 (S.D. W. Va. Feb. 8, 2017) ("Ethicon first argues that I should exclude Dr. Walmsley's testimony because he does not identify a general causation foundation for his specific causation opinion.").

Now, having previously argued that specific causation testimony **requires** a general causation foundation, Ethicon is attacking Dr. Wallach for providing exactly that. Clearly, these are contradictory arguments. In explaining: 1). how Ethicon's mesh reacts in the human body, 2). the potential complications it can cause, 3.) whether potential complications are disclosed in the IFU, and 4). what safer alternatives to the Prolift exist, Dr. Wallach is providing information that informs her case-specific opinions. In other words, she is doing exactly what Rule 26 requires: providing "a complete statement of all opinions the witness will express and the basis and reasons for them" and providing "the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B)(i)-(ii). It would be absurd to exclude the foundation for Dr. Wallach's case-specific opinions, when the rules require that the foundation be disclosed, and when Ethicon has previously asserted the need for such a foundation by attempting to label these foundational opinions as "general" opinions. This is entirely a contrived issue. The fact that Defendants' have filed a nearly-identical *Daubert* motion and memorandum in the Larson case, styled as a motion to limit her case-specific opinions, is illustrative of the fact that this is entirely a contrived issue. *See* Case 2:14-cv-22872, Dkts. 48,49.

For the above reasons, the Court should deny Ethicon's motion on this point.

II. Any issues regarding Legal Conclusions, Legal Terms of Art, Opinions Regarding Corporate Conduct, and "Complications not Experienced by Plaintiff" should be addressed at trial.

Plaintiffs acknowledge that this Court has consistently held that experts may not offer legal conclusions as part of their testimony. However, Defendants go too far in trying to prevent

Dr. Wallach from opining that Ethicon's devices have "known problems." This Court should hold that these issues should be addressed with objections in the context of trial.

The Fourth Circuit rule on legal conclusions is stated as follows: "We identify improper legal conclusions by determining whether "the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). For instance, "unreasonably dangerous" would probably qualify as a legal conclusion under that standard, but "flawed" clearly would not. Rather than parse out Dr. Wallach's report, this Court should issue a general prohibition on legal conclusions and let the trial judge sort out what is, or is not, a legal conclusion based on objections at the time of trial.

With regard to complications not experienced by Plaintiff, Defendants' claim that Dr. Wallach offers opinions regarding complications not experienced by Ms. Larson, including "complications such as fistula formation, infection of the mesh, bladder/vaginal/pelvic infections caused by mesh, nerve damage pudendal neuralgia, and other complications experienced by Ms. Larson". Def. Memo at 4-5. As an initial matter, this list of complications which Defendants' allege Ms. Larson has not experienced is not even accurate. For example, Dr. Wallach specifically opines that Ms. Larson had never damage from repetitive vaginal surgeries with mesh placement and mesh removal twice, resulting in rectal incontinence. Dkt. 8994-1, Wallach Report at page 30. Dr. Wallach has also opined that Ms. Larson may require future surgeries, and may have future erosions as she still has mesh in her body. *Id*. at 31. An eroded mesh can surely cause bladder/vaginal/pelvic infections. In addition, a complication "not experienced" can be relevant to the Plaintiffs' failure to warn claims if the Plaintiff testifies that they never would have had the mesh implanted if they had been warned of a particular complication. Moreover,

complications which can be caused by the Prolift but not actually experienced by the Plaintiff can be relevant to what safer alternatives existed to the Prolift, and the relative risk-utility of those alternatives as discussed in section IV below. In Minnesota, The risk-utility balancing test for design defects necessarily "focuses on the conduct of the manufacturer in evaluating whether its choice of design struck an acceptable balance among several competing factors." *Bilotta v. Kelly Co., Inc.*, 346 N.W.2d 616, 622 (Minn.1984). Again, rather than parse out Dr. Wallach's report, this Court should reserve ruling on this issue, and let the trial judge sort out what is relevant and probative with regard to failure to warn claims and risk-utility analysis, and what complications the Plaintiff actually has or has not experienced, or may be at future risk of experiencing.

III. Dr. Wallach is qualified to render opinions regarding Ethicon's Warnings, and the interaction of those warnings in the informed consent process. Dr. Wallach has laid the foundation for her opinions.

A. Dr. Wallach is well-qualified, and in fact, uniquely qualified to offer opinions regarding the adequacy of the Prolift IFU, as she has trained residents on the procedure.

In Section III. of its Motion, Defendant argues that Dr. Wallach is not qualified to render opinions relating to the adequacy of product warnings and her opinions are not reliable. Specifically, Ethicon contends that Dr. Wallach is not an expert in warnings, and that she has never had a proctoring for consulting relationship with any mesh device manufacturer, except for AMS. These arguments are unfounded, and misstate the appropriate standard for offering warnings opinions.

Dr. Wallach's expertise in female pelvic health and reconstructive surgery is beyond serious question. Dr. Wallach explains that she has reviewed numerous Instructions for Use (IFU) for a variety of medical products, including mesh products, in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events

associated with the devices. (Dkt. No. 8994-1, pp. 3, 5-7, 24). In fact, while the device was still on the market, Dr. Wallach had a complete Prolift Total kit in her office including the IFU given to her by an Ethicon representative, and used that material to train her residents. *Id.* at 3.

Based on her extensive qualifications, knowledge, training and experience, as well as her review of the Ethicon Prolift IFUs and the medical literature, Dr. Wallach provides her opinions concerning the adequacy of the Prolift warnings, and she explains the basis for those opinions in detail. *Id*. at 24-26. Dr. Wallach's qualifications and process of evaluating the adequacy of the IFU is similar to the qualifications and process that this Court approved in *Huskey v. Ethicon* and other cases. Addressing a *Daubert* challenge against plaintiff's proposed expert, Dr. Rosenzweig's, warning opinions, this Court stated:

> In his expert report, Dr. Rosenzweig states that he has reviewed "numerous" IFUs for a "variety of products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the device." ... . Further, as a urogynecologist, Dr. Rosenzweig is qualified to opine about the risks of the TVT-O and pelvic mesh surgery and whether those risks were adequately expressed on the TVT-O's IFU. I therefore FIND that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials.[2]

Similarly, this Court approved a plaintiff's expert, Dr. Blaivas, to testify about warnings for BSC products in *Tyree v. Boston Scientific Corporation.*

> [A]s a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warnings and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-O was when the warnings were published.

More recently, in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *13-*14 (S.D. W. Va. May 19, 2016), the Court similarly observed that "[a] urogynecologist … is qualified to

[2] *Huskey v. Ethicon, Inc.*, 2014 WL 3362264 at *5 (S.D. W. Va. July 8, 2014)).

make this comparison [whether the product's warnings convey the risks the product poses to patients]." *Accord Franco v. Boston Scientific Corp.*, 2016 WL 3248505, at *15 (S.D. W. Va. Jun. 13, 2016).

In *In re Yasmin and Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11-*13 (S.D. Ill. Dec. 16, 2011), the drug manufacturer argued that the plaintiffs' proffered experts, both Obstetrician-Gynecologists, were not qualified to offer opinions regarding the adequacy of its labeling, and further that their opinions were not based on any reliable methodology. The Court rejected its argument, and held instructively as to one of the OB-GYN experts as follows:

> As a practicing OB/GYN tasked with making prescription decisions on a daily basis, Dr. Bercy-Roberson is qualified to opine as to how certain knowledge, obtained through studies, reports, and internal Bayer documents, would have affected her previous prescription-related decisions. Dr. Bercy-Roberson does not require expertise in FDA regulations to opine in this manner, as she does not comment on the conduct of the FDA. Further, doctors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs]…and to compare that knowledge with what was provided in the text of labeling and warnings for FDA approved drugs.' *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, *11 (E.D. Pa. June 20, 2000). Thus, Dr. Bercy-Roberson is qualified to render an opinion as to the drug label's completeness and accurateness. *See id*....
>
> Thus, as Dr. Bercy-Roberson's opinion based on peer-reviewed sources and data, her methodology is sound. The correctness of her opinion is left to the trier of fact's determination.

Id. See also Smith v. Wyeth-Ayerst Laboratories Co., 278 F. Supp. 2d 684, 702 (W.D.N.C. 2003) (citing *In re: Diet Drug* MDL PTO 1332, wherein the MDL court concluded physicians are "'qualified to render an opinion as to the labels' completeness, accuracy, and ... the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits ... are or were at the time the labeling was published.'"); *accord, Burton v. Wyeth-Ayerst Labs. Div. of Amer. Home Prods. Corp.*, 513 F. Supp. 2d 708, 712 (N.D. Tex. 2007); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 556 (S.D.N.Y. 2004) ("Pursuant to

the defendants' concession [in light of *In re: Diet Drugs*], and subject to relevance rulings to be made by the trial courts, these [physician expert] witnesses are not precluded from offering otherwise admissible testimony as to the accuracy of the Rezulin label."); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1063-64 (D. Minn. 2007) (citing *In re: Diet Drugs* opinion in denying defense *Daubert* motion to exclude physician expert opinion regarding drug labeling, stating that "[t]he Court agrees that [the plaintiffs' physician expert] is qualified to render an opinion regarding the completeness or accuracy of the Baycol label based on his knowledge of the risks of Baycol and his own clinical experience").

As in the several cases cited above, and per this Court's prior rulings, Dr. Wallach is well-qualified to provide opinions about the risks associated with Ethicon's Prolift products and "whether those risks were adequately expressed" in the Prolift IFUs and "the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" were when the IFUs were published. Defendants' challenge to Dr. Wallach's qualifications should be rejected.

Dr. Wallach offers her opinion that the Prolift IFU should have contained additional warnings and information. Moreover, Dr. Wallach's opinions are consistent with Ethicon's own actions in updating the IFU in 2015 for Gynemesh PS (the mesh used in the Prolift), to include a number of significant adverse events which were never disclosed in the Prolift IFU. For example, with regard to the Prolift, Dr. Wallach states in her report that "Ethicon failed to provide any warning about the frequency or extent of mesh shrinkage known to be associated with polypropylene mesh." (Dkt. No. 8994-1, p. 25). In fact, after the Prolift was removed from the market, Ethicon did update the IFU for the mesh used in the Prolift to include a statement warning about the extent of mesh shrinkage that could occur with the mesh, warning that

"**Excessive** contraction or shrinkage of the tissues surrounding the mesh, vaginal scarring, tightening, and/or shortening may occur." (*See* Ex. 2, Gynemesh PS IFU released Feb. 3, 2015, p. 3) (emphasis added). This warning never appeared in the Prolift IFU. (*See* Ex. 3, Prolift IFU at discontinuance, *compare with* Ex. 2). Ethicon's own actions in updating and strengthening the warnings for the Prolift mesh (Gynemesh PS) in 2015, after the Prolift device was pulled off the market, support Dr. Wallach's opinions that the warnings for the Prolift mesh were inadequate while it was being sold.

As set forth in her Report, Dr. Wallach bases her opinions on her own demonstrated education, knowledge, training, and teaching experience, as well as on information contained within the published medical literature. Dr. Wallach's opinions are thus substantially similar to the opinions of other urogynecologists which this Court has allowed concerning the adequacy of warnings. As this Court has noted:

> I further **FIND** that this opinion is sufficiently reliable. Dr. Rosenzweig relies on an internal Ethicon finding that the mesh used in the TVT–O was cytotoxic. Further, Dr. Rosenzweig states that the potential for cytotoxicity is important information that physicians need to know. . . . To the extent that Ethicon believes cytotoxicity is not clinically significant, it may cross examine Dr. Rosenzweig on that issue.[3]

Like Dr. Rosenzweig, Dr. Wallach relies on her education, training, skill and experience as well as his review of what information was known or available to Ethicon to support her opinions regarding Ethicon's warnings. While Defendants couch their challenge otherwise, in reality Ethicon is challenging the validity of the information relied upon by Dr. Wallach, or the accuracy of her conclusions based on such information. As such, Ethicon's motion goes to the weight, not the admissibility, of Dr. Wallach's testimony. *In re St. Jude Medical, Inc. Silzone Heart Valves Prods. Liab. Litig.*, 493 F. Supp. 2d 1082, 1089 (D. Minn. 2007) ("As a general

[3] *Huskey*, 2014 WL 3362264 at * 6.

rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination."); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601-02 (S.D. W. Va. 2013) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (the *Daubert* inquiry focuses solely on "the 'principles and methodology' employed by the expert, not on the conclusions reached."). Ethicon will have ample opportunity to cross-examine Dr. Wallach on these issues. Ethicon's motion to exclude should be denied as to her opinions about the IFU.

IV. Dr. Wallach's Opinions Regarding Safer Alternative Treatments for the Prolift are Relevant, and Consistent with the Current Treatment Guidelines of Multiple Physician Groups.

Defendants' challenge Dr. Wallach's opinions that there are safer alternatives to the Prolift not because it is incorrect, but because she "does not cite a single study or reliable basis for such an opinion."[4] The fact that there are multiple safer alternative treatments to the Prolift for pelvic organ prolapse is so well accepted that multiple physician groups, including the American College of Obstetricians and Gynecologists ("ACOG"), to which Dr. Wallach belongs and was an oral examiner for board certification exams, has stated that: "Compared with native tissue anterior repair, polypropylene mesh augmentation of anterior wall vaginal wall prolapse repair improves anatomic and some subjective outcomes, but is associated with increased morbidity. Vaginally placed polypropylene mesh is associated with longer operating times and greater blood loss compared with native tissue anterior repair. In addition, the use of vaginally placed polypropylene mesh is associated with an increased risk of repeat surgery for prolapse, stress urinary incontinence and mesh exposure." (*See* Ex. 4. ACOG/AUGS Joint Practice Bulletin 214, Issued November 2019). The ACOG/AUGS practice bulletin also found that compared with native tissue anterior repair, mesh augmentation is associated with increased

[4] Defendant's Memo in Support of Motion at p. 9.

morbidity, and that the use of synthetic mesh in pelvic organ prolapse surgery is associated with unique complications not seen in POP repair with native tissue. *Id*.

Other Physician treatment groups have rejected the use of transvaginal mesh for the repair of pelvic organ prolapse such as the Prolift as well, including the Canadian Urological Association, which has found that: "The currently available literature does not support the routine use of transvaginal mesh for prolapse repair. This recommendation does not apply to the use of transabdominal mesh used during a minimally invasive or open sacrocolpopexy." (*See* Ex. 5. Canadian Urological Association position statement on the use of transvaginal mesh, June 2017). The National Institute for Health and Care Excellence has found that: "Current Evidence on the safety of transvaginal mesh repair of anterior or posterior vaginal wall prolapse shows there are serious but well-recognised safety concerns. Therefore, this procedure should only be used in the context of research." (*See* Ex. 6, NICE Interventional procedures guidance Dec, 2017) (Emphasis added). The FDA recently banned **all** transvaginal mesh kits that were still on the market for the repair of Pelvic Organ Prolapse, finding that they had not demonstrated a reasonable assurance of safety and effectiveness, and there was no evidence that they worked better than surgery without the use of mesh to repair Pelvic Organ Prolapse. (*See* Ex. 7, FDA press release dated April 16, 2019). Dr. Wallach's opinions regarding safer alternative treatment and procedures to the Prolift is simply informing the jury of what is now common knowledge to the majority of the medical community: that a native tissue prolapse repair using biologic grafts rather than synthetic mesh, or an abdominal sacrocolpopexy using mesh, are safer surgical interventions that transvaginal mesh kits like the Prolift.

Ethicon next tries to exclude the overwhelming evidence that there are alternative non-surgical and non-mesh safer procedures to the Prolift on the grounds that it does not inform on

the issue of whether an alternative design for a product exists.[5] First, this is not the appropriate standard under *Daubert*, and the testimony should be allowed as it is factually correct and based on reliable methodology. Second, excluding this opinion would contradict and obfuscate from the jury the current practice and standard of care for the treatment of pelvic organ prolapse at this time--that transvaginal mesh kits like the Prolift are no longer used due to significant safety concerns. Finally, it ignores the fact that in this unique case, evidence about alternative surgical procedures should be considered as a safer alternative design because Prolift is itself both a procedure AND a product, and is not merely a product.

Prolift is itself a vaginal *procedure* that uses a polypropylene product as a support mechanism to treat POP. It would be a legal fiction to segregate the transvaginal procedure used to implant Ethicon's product—as it is sold as a "kit" that includes unique surgical tools to perform Ethicon's prescribed surgical procedure, the instructions on how to perform that procedure, and the Polypropylene mesh. Ethicon's "Surgical Technique" Guide for the "Prolift Pelvic Floor Repair System" clearly characterizes Prolift as a *procedure*. (*See* Ex. 8, Prolift Surgical Technique Guide, at page 2 (noting, for example, that "[t]he objective of the PROLIFT procedure is to achieve a complete anatomic repair of pelvic floor defects in a standardized way."). This product was not marketed by Ethicon as merely a mesh *product*, but rather Ethicon sold it as the "Prolift Pelvic Floor Repair System."[6] The fact that Prolift is a procedure, as well as a polypropylene product, is admitted by Ethicon. For example, Ethicon Medical Affairs Director Axel Arnaud testified that Prolift was developed as an alternative procedure to

[5] Defendant's Memo in Support of Motion at p. 10.
[6] *Id.*

colporrhaphy to treat prolapse."[7] And Ethicon's own marketing materials for the Prolift refer to it as a "procedure."[8]

While Ethicon cites authority regarding the TVT device, which is not a product at issue in Dr. Wallach's Prolift report, there are multiple examples from the MDL court which have allowed evidence of non-mesh alternatives. *See, e.g., Campbell v. Boston Sci. Corp.*, No. 2:12-CV-08633 WL 5796906, at *4 (S.D. W. Va. Oct. 3, 2016) (crediting testimony on alternative designs, including the Burch colposuspension and pubovaginal slings, in rejecting motion for JNOV); *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2104 WL 186869, at *7 (S.D. W. Va. Jan 15, 2014), *rev'd in part sub nom. In re Ethicon, Inc.*, No. 2:12-CV-4301, 2014 457551 (S.D. W. Va. Feb. 3, 2014) (listing "mesh constructed from native tissue" as an alternative design to the TVT); *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-CV-4301, 2014 WL 505234, at *2 (S.D. W. Va. Feb. 5, 2015) (noting the importance of testimony about Burch colposuspension on the issue of safer alternative designs).

Moreover, the question of whether Dr. Wallach's proposed alternatives qualify as products, as procedures, or as some combination thereof is immaterial to the question of whether they are relevant to the case. Motions based on relevance are particularly ill-suited for general Daubert motions, because relevance may vary greatly depending on the state law involved. However, In two separate pelvic mesh cases under Illinois law, courts have recognized that even alternative procedures are relevant to issues relating to design defects. *See, e.g., Herrera-*

[7] *See* Ex. 9, Deposition of Ethicon Medical Affairs Director Axel Arnaud (November 11, 2015) at 292:21-293:10.

[8] *See* Ex. 10, (Prolift Brochure) (noting that "[w]ith GYNECARE PROLIFT, pelvic floor repair can be completed in less than half the time of traditional surgery. Patients also may go home the next day and may experience less pain and quicker recovery. The ***procedure*** is designed to restore normal anatomy…") (emphasis added).

Nevarez v. Ethicon, Inc., No. 12 C 2404, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017)[9]; *Wiltgen v. Ethicon, Inc.*, No. 12-CV-2400, 2017 WL 4467455, at *4 (N.D. Ill. Oct. 6, 2017). As those courts recognized in ruling on the admissibility of similar expert testimony, the existence of alternative procedures is highly relevant to the utility of the design. In other words, that information helps to answer the question, is there a better way to solve this problem? *See Wiltgen*, 2017 WL 4467455, at *4 ("Plaintiffs are correct, however, in arguing that this evidence is nonetheless relevant to determine if a product is unreasonably dangerous."); *Herrera-Nevarez*, 2017 WL 3381718, at *7 (holding that "the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product").[10] Like Illinois, Minnesota also applies a risk-utility test to product defect cases. The risk-utility balancing test for design defects necessarily "focuses on the conduct of the manufacturer in evaluating whether its choice of design struck an acceptable balance among several competing factors." *Bilotta v. Kelly Co., Inc.*, 346 N.W.2d 616, 622 (Minn.1984).

Dr. Wallach's opinions regarding safer alternatives to the Prolift are supported by the medical community, helpful to the jury, and should be allowed.

V. Ethicon has mis-characterized Dr. Wallach's opinions regarding the difficulty of the blind passage of the metal trocars of the Prolift and the difficulty in removing Prolift Mesh as Opinions on the Competence of Other Physicians. These Opinions Should be allowed.

As discussed, *supra*, Dr. Wallach is uniquely qualified to testify as to the difficulty of the blind passage of the metal trocars of the Prolift, due to the fact that she trained residents on the

[9] The court's analysis was in reference to Dr. Daniel Elliot, but as the court wrote in addressing Dr. Rosenzweig's testimony immediately thereafter, the issue is exactly the same regardless of the expert involved.

[10] Alternative procedures are also relevant to consumer expectations, as consumers would likely expect the surgery to be at least as safe as more established surgical procedures.

Prolift and has placed the Prolift mesh (Gynemesh) in patients, as well as multiple other trocar-based transvaginal mesh systems. (Dkt. No. 8994-1, pp. 2-3). Dr. Wallach testifying as to her own personal experience in training and observing residents, as well as her own experience in using trocar-systems for POP repair, is not an opinion on the "competence of other physicians" as Ethion suggests, but merely her opinion based on her clinical experience performing these surgeries and training residents. The same can be said for her opinions on the difficulty in removing pelvic mesh. This is based on her extensive experience removing mesh, and the fact that she is referred many complex medical cases from her region, as Dr. Wallach is at a tertiary care academic medical center. Defendants create a straw man regarding Dr. Wallach's intended testimony on these topics by attempting to characterize them as opinions on the competence of other physicians, when they are not. They are simply opinions on the difficulty of performing the Prolift procedure, and the difficulty in treating complications from the Prolift mesh based on Dr. Wallach's experience, observations, discussions with colleagues, and the medical literature. She draws from her clinical experience and the relevant medical literature to determine that the product benefits outweigh the product risks, and that it is difficult to use and difficult to remove the mesh when necessary. This Court has determined that such experience is sufficient for opinions of this nature. *See Trevino v. Boston Scientific Corp*., 2016 WL 1718836, *6 (S.D. W. Va. April 28, 2016).

CONCLUSION

For the reasons set forth above, the Court should deny Defendants' Motion to Exclude the "General" Opinions of Stacey Wallach. M.D.

Dated: January 3, 2020

Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on January 3, 2020, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Thomas P. Cartmell
Attorney for Plaintiffs